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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ROSENWALD, STEVEN ERIC	

ART UNIT	PAPER NUMBER
1759	

NOTIFICATION DATE	DELIVERY MODE
10/11/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,745	BARLAG ET AL.	
	Examiner	Art Unit	
	STEVEN ROSENWALD	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 September 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1 - 26 and 29* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1 - 26 and 29* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 – 29 are presented for examination. Claims 1, 5, 9, 10, 25, and 26 have been amended. Claims 27 and 28 are cancelled.

Status of Objections and Rejections

1. The objection to the specification is withdrawn due to Applicant's amendment.

2. The objection to claim 25 is withdrawn due to Applicant's amendment.

3. The rejection of claim 26 under 35 USC § 112 is withdrawn due to Applicant's amendment.

4. Claim 1 has been amended and is the sole independent claim. New rejections of claims 1 – 26 and 29 are made.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 12, 17, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over et al. US 5,635,054 ('054) in view of Bentsen et al. US 2002/0195345 A1 ('345).

Regarding claim 1, '054 teaches a biosensor (col. 3 lines 27 – 31, col. 7 lines 7 – 9) operating on an electrochemical detection principle (col. 3 lines 56 – 57), comprising

a transducer array (col. 1 lines 53 – 57, and col. 3 lines 23 – 26) containing a flexible metal/isolator composite (col. 1, line 51 and col. 3 lines 17 – 18) composed of a metal layer (col. 2 lines 24 – 25, "the conducting material is suitably a thixotropic paste based on carbon *or metallic particles (e.g. platinum or gold)*") and an isolator layer (col. 1 lines 47 – 50) with a permanent connection between a surface of the metal layer and a surface of the isolator layer (col. 2 lines 31 – 32, col. 5 lines 10 – 13 and Figs. 1 and 2), the metal layer being in the form of a self-supporting metal substrate (col. 5 lines 10 – 13 and col. 3 lines 17 – 18) and being structured in such a manner that metal areas which are electrically isolated from one another are produced (col. 3 lines 23 – 26), the isolator located on the metal substrate (col. 5 lines 10 – 13), being structured in such a manner that open metal surfaces remain as sensor surfaces in the isolator surface (Abstract and Figs. 1 and 2), discrete electrodes the metal areas each including associated individual measurement electrodes on the one hand and at least one reference electrode on the other hand (col. 3 lines 23 – 26 and claim 12).

However, '054 does not teach the structured metal areas are contactable with, on a side facing away from or opposite the sensor surface. Bentsen ('345) teaches (par. 0017 and Fig. 4D) electrodes ... may be connected ... on the first and second surface of the flexible polymeric substrate. "Second surface" reads on the claim. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify the microelectrode array of '054 with the second surface connection of '345 in order to enable the first surface bearing the exposed electrodes to be directly laminated to a fluid handling architecture that directs the fluid sample to the electrode array,

overcome arduous wire bonding processes and overcome the need to encapsulate the lead wires in a protective material as taught by '345 (par. 0017).

Regarding claim 12, '054 teaches (claim 13) that the reference electrode is an Ag/AgCl electrode.

Regarding claim 17, '054 teaches (a)n assay device ... which is connected to a potentiostat (col. 4 lines 41 – 43).

Regarding claim 29, '054 teaches (col. 2 lines 24 – 25) conducting material is suitably a thixotropic paste based on carbon or metallic particles.

6. Claim 1 – 21 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen et al. US 2002/0195345 A1 ('345) in view of Girault et al. US 5,635,054 ('054).

Regarding claim 1, '345 teaches a biosensor (par. 0011) operating on an electrochemical detection principle (par. 0025), comprising:

a transducer array (par. 0011), containing a flexible metal/isolator composite composed of a metal layer and an isolator layer (par. 0012) with a permanent connection between a surface of the metal and a surface of the isolator layer (par. 0051 and Fig. 4A), the metal layer being in the form of a self-supporting metal substrate (par. 0014) and being structured in such a manner that metal areas which are electrically isolated from one another are produced (par. 0015, 0027, 0043, 0051),

the isolator located on the metal substrate, structured in such a manner that open metal surfaces remain as sensor surfaces in the isolator surface (par. 0014) wherein,

the structured metal areas are contactable with, on a side facing away from or opposite the sensor surface (par. 0017, Fig. 4D), discrete electrodes, the metal areas each including associated individual measurement electrodes on the one hand (par. 0012).

Bentsen in '345 is silent on at least one reference electrode. However, Bentsen does teach detection of electrical signals in response to biological events at the individual electrodes (par. 0024), that the charge potential of the electrodes can be individually controlled (par. 0027), enzyme based electrodes (par. 0083), and analysis of antibody/antigen reactions (par. 0011).

'054 teaches (col. 3 lines 23 – 26) that electrodes can be individually addressed to a set electric potential, (col. 3 lines 28 – 31) immobilization of reactants (enzyme or antibody) onto the insulating area by covalent bonding allowing direct application to biosensor and biochemical assay technology, a (col. 6 line 18) counter electrode (reads on reference electrode) for (col. 6 lines 42 – 47) voltammetric analysis with a working electrode and a controlled voltage secondary electrode (reads on reference electrode), and (claim 12 and see Figs. 6 and 7) a reference electrode. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify the biosensor of '345 with the reference electrode of '054 in order to enable the detection of electrical signals in response to biological events such as the enzyme based electrodes of '345 using voltammetry as taught by '054 (col. 3 lines 32 – 34 and col. 7 lines 6 – 14). Regarding claim 12, '054 teaches (claim 13) that the reference electrode is an Ag/AgCl electrode.

In regard to claims 2 – 26 and 29, '054 and '345 teach the device of claim 1 and;

Regarding claim 2, '345 teaches (par. 0051, 36 at Fig. 4C) vias (reads on cavities) wherein portions of substrate are removed or "milled" away from each of the electrodes, thereby exposing bare metal, and '054 teaches (col. 1, lines 47 – 50) apertures (reads on "cavities") formed in the layer of electrically insulating material and electrically conducting material visible through the apertures.

Regarding claim 3, '345 teaches (par. 0017) electrodes formed by exposure to the metal layer may be connected by metal traces to much larger contact pads located elsewhere on the first or second surface of the flexible polymeric substrate. "Second surface" reads on "opposite side".

Regarding claim 4, '345 teaches (par. 0017) electrodes formed by exposure to the metal layer may be connected by metal traces to much larger contact pads located elsewhere on the first or second surface of the flexible polymeric substrate. "First or second surface" reads on "exposed on both sides".

Regarding claim 5, '345 teaches (par. 0017) electrodes formed by exposure to the metal layer may be connected by metal traces to much larger contact pads located elsewhere *on the first or second surface* of the flexible polymeric substrate. "connected by metal traces to much larger contact pads located elsewhere" reads on "the contacts are laterally offset".

Regarding claim 6, '345 teaches (par. 0027) a plurality of electrodes and that the charge potential of the electrodes preferably can be individually controllable, and '054 teaches *apertures or groups of apertures* (with apertures created to expose electrode surfaces, see Abstract) within an array can be individually addressed to a set electric

potential (col. 3 lines 23 – 24) and (col. 6 lines 14 – 22 and Figs. 6 and 7) a single sensor device comprising two electrodes with two electrically isolated metal areas.

Regarding claim 7, '345 teaches (Figures 2A, 2B, and 8E) microelectrodes extend through the flexible polymeric substrate from bottom surface to top surface to define corresponding microlocations (par. 0049) and that the substrate can have more than one layer and the metal traces may be positioned on one or more layers (par. 0055).

Regarding claim 8, '345 teaches (par. 0027) a plurality of electrodes and that the charge potential of the electrodes preferably can be individually controllable.

Regarding claim 9, '345 teaches (par. 0016) electrodes enlarged by deposition of additional metal … such as gold, and (par. 0052) (s)uitable metals include aluminum, gold, silver, tin, copper, palladium, platinum, carbon and various metal combinations (reads on noble metal alloy), and '054 teaches (col. 3 lines 17 – 18) electrodes can be made from different conducting materials (e.g. platinum, gold, carbon etc.).

Regarding claim 10, '345 teaches (par. 0016) electrodes enlarged by deposition of additional metal (reads on "coated with") … such as gold (noble metal) and (par. 0052) various metal combinations (reads on "alloy").

Regarding claim 11, '345 teaches (par. 0052) carbon (reads on graphite) and '054 teaches (col. 2 lines 6 – 8) a particular advantage when the electrode material includes carbon, since one photo-ablation used to form the apertures can vitrify (make glassy) one carbon in the areas of electrode material and teaches (col. 2 lines 24 – 25)

(t)he conducting material is suitably a thixotropic paste based on carbon, which reads on the instant claim.

Regarding claim 13, '345 teaches (par. 0096) providing an electrolyte (sentence 1 reads on electrolyte), which prima facie wets electrodes (plural) and that "BSA was positively charged and accumulated at negatively biased electrodes" which reads on the instant claim.

Regarding claim 14, '345 teaches (par. 0046) (a) biasing signal (voltage or current) is applied to selected electrodes, thereby accelerating transport of the target species into the hydrophilic matrix above the selected electrodes. The biasing voltage is subsequently stopped, with the target species concentrated at one *or more* of the microlocations, which reads on the instant claim.

Regarding claims 15 and 19, a person having ordinary skill in the art at the time of invention would have basic knowledge of the electrochemical circuits associated with the use of a potentiostat, including a two electrode cell, which includes a working and counter electrode, and a three electrode cell, which includes a working, counter, and reference electrode. (See, for example, Bard and Faulkner, Electrochemical Methods, 1980, John Wiley & Sons pages 136, 137, and 563 attached.) Girault in '054 teaches (a)n assay device … which is connected to (e.g. plugged into) a suitable potentiostat (col. 4 lines 41 – 43), a working electrode (col. 6 line 43), a microelectrode and a counter electrode (col. 4 lines 50 – 51), and a reference electrode coated with silver chloride (claim 13), and '054 also teaches that groups of apertures (with apertures created to expose electrode surfaces, see Abstract) within an array can be individually

addressed to a set electric potential (col. 3 lines 23 – 24) and the use of an electrode made by the method of this invention for redox species analysis using voltammetry (col. 3 lines 32 – 34). Therefore, since a person of ordinary skill in the art at the time of invention would know that a potentiostat may be used in a two- or three-electrode configuration it would have been obvious to a person of ordinary skill in the art at the time of invention to configure the device as cited in claim 15.

Regarding claim 16, 345 teaches (par. 0096) providing an electrolyte (sentence 1 reads on electrolyte), which prima facie immerses the electrodes, and (par. 0017) the first surface bearing the exposed electrodes can be directly laminated to a fluid handling architecture that directs the fluid sample to the electrode array, and '054 teaches (t)he micro-conducting areas of the electrode will be carbon and the (reference) electrode will be of silver/silver chloride and a sample of the water to be tested … will dissolve the salt and redox reagent (reads on electrolyte) forming a conductive solution between the electrodes (col. 6 lines 36 – 42).

Regarding claim 17, electrodes taught in the art as combined above can be connected to a potentiostat, therefore '345 is connectable.

Regarding claim 18, '345 teaches (par. 0017) electrodes connected to contact pads designed to mate directly with a voltage control unit, and (par. 0024) the voltage control unit simultaneously can provide processing currents or voltages, and (par. 0046) a biasing signal (voltage or current) is applied to selected electrodes, and '054 teaches (col. 4, lines 3 – 4) a programmed voltage scan (ramp or step formed) is used for the concentration measurement.

Regarding claim 20, '345 teaches (par. 0018) electrodes may be recessed within the vias (reads on cavities) in the flexible polymeric substrate, that biomolecules can be immobilized within the vias, and that biologically active molecules (par. 0022) are covalently anchored such that they are in contact with the array of electrodes (par. 0026), and '054 teaches (col. 3 lines 27 – 31) chemical immobilization of reactants (enzyme or antibody) onto the insulating area by covalent bonding in close proximity (col. 7 lines 12 – 13) between the electrode and the immobilized species (which reads on the instant claim).

Regarding claim 21, '345 teaches (par. 0056 and see Fig. 9, below) fluid handling architecture that is designed to confine a specified volume of sample-containing fluid as (a) single fluid volume over (an) array of microlocations, defined as (a) sample chamber.

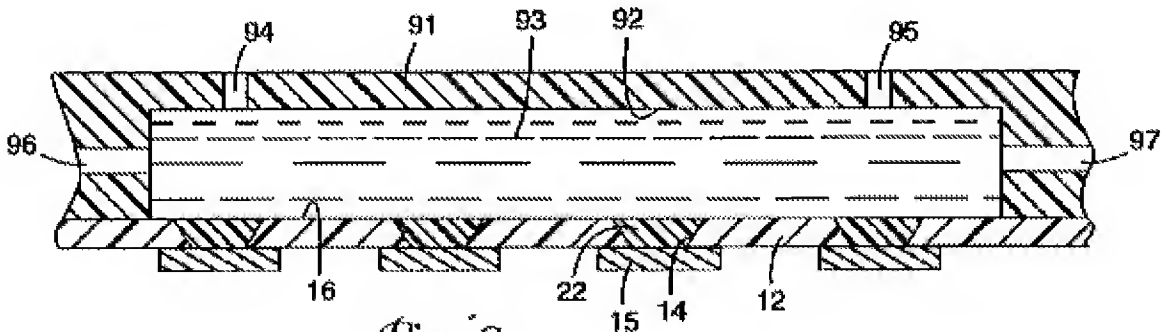

Fig. 9

As described in Fig. 9, 4 electrodes (15) are shown in the confined sample area (reads on cavity), although only one is labeled. Further, '054 teaches (col. 3 lines 23 – 26) that Apertures or groups of apertures within an array can be individually addressed to a set electric potential and therefore the electrode array could be used in multicomponent determination simultaneously

Regarding claim 29, '054 teaches (col. 2 lines 24 – 25) conducting material is suitably a thixotropic *paste based on carbon* or metallic particles and (col. 5 lines 19 – 20) a layer (of) cured carbon paste of a cured thickness of 500 microns. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify the device of '345 with the carbon paste of '054 so that where the paste is applied to a pre-drilled sheet of plastics material each aperture formed in the non-conducting sheet is substantially filled with conducting particles as taught by '054 (col. 2 lines 26 – 29).

7. Claims 22 – 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bentsen et al. US 2002/0195345 A1 ('345) in view of Girault et al. US 5635054 ('054) as applied to claims 1 – 21 above, and further in view of Hodges et al. US 2005/0173246 A1 ('246).

Bentsen et al. US 2002/0195345 A1 ('345) and Girault et al. US 5635054 ('054) are relied upon for the reasons given above, but neither teaches a separate metal surface closing a cavity.

Regarding claim 22, Figures 6 and 7 and the text at column 4 lines 27 – 49 of '054 teaches a working and reference electrode with a measurement area between them, and '345 teaches an enclosed sample chamber (par.0056 and Fig. 9 below, see claim 24), but '054 and '345 do not disclose a separate metal surface closing a cavity. However, Hodges teaches (par. 0050 and Fig. 1) a biosensor in the form of a thin strip membrane 1 having upper and lower surfaces 2, 3 and having a cell zone 4 defined between a working electrode 5 disposed on upper surface 2 and a counter electrode 6

disposed on lower surface 3. Hodges also teaches (par. 0002) (e)lectrochemical biosensors generally comprise a cell having a working electrode, a counter electrode and a reference electrode. Sometimes the function of the counter and reference electrodes are combined in a single electrode called a "counter/reference" electrode.

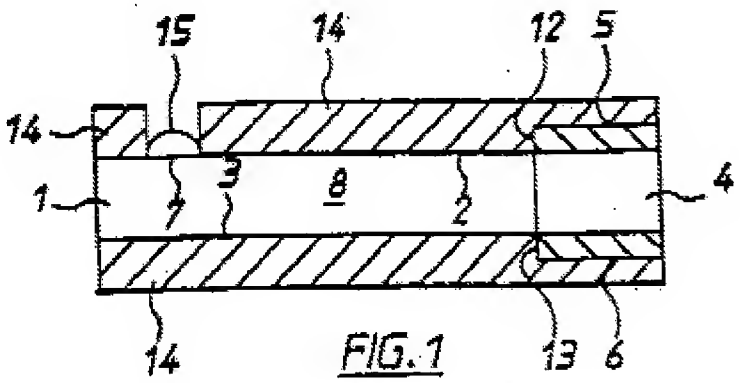

FIG. 1

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of invention to modify the biosensor of '345 in view of '054 with the working electrode disposed on upper surface and a counter electrode 6 disposed on lower surface of '246 so that the electrodes are separated by a distance "1" which is sufficiently close that the products of electrochemical reaction at the counter electrode migrate to the working electrode during the time of the test and a steady state diffusion profile is substantially achieved as taught by Hodges (par. 0050).

Regarding claim 23, '345 teaches (par. 0017) electrodes connected to contact pads designed to mate directly with a voltage control unit, and (par. 0024) the voltage control unit simultaneously can provide processing currents or voltages, and (par. 0046) a biasing signal (voltage or current) is applied to selected electrodes, and '054 teaches (col. 4, lines 3 – 4) a programmed voltage scan (ramp or step formed) is used for the

concentration measurement, and '246 teaches (par. 0011) applying an electric potential difference between the electrodes.

Regarding claim 24, '345 teaches (par. 0056 and see Fig. 9, above) fluid handling architecture that is designed to confine a specified volume of sample-containing fluid as (a) single fluid volume over (an) array of microlocations, defined as (a) sample chamber.

As described in Fig. 9, 4 electrodes (15) are shown in the confined sample area (reads on cavity), although only one is labeled. Further, '054 teaches (col. 3 lines 23 – 26) that Apertures or groups of apertures within an array can be individually addressed to a set electric potential and therefore the electrode array could be used in multicomponent determination simultaneously, and '246 teaches a working electrode disposed on upper surface and a counter electrode disposed on lower surface in Fig. 1 of '246 and that (par. 0002) (e)lectrochemical biosensors generally comprise a cell having a working electrode, a counter electrode and a reference electrode. All 3 devices are considered to read on the instant claim.

Regarding claim 25, for examination purposes claim 25 is considered to be dependent on claim 22. '054 teaches (claim 13) a silver/silver chloride reference electrode and '246 teaches (par. 0081) silver halide (reads on chloride) may also be used to form the counter/reference electrode.

Regarding claim 26, claim 26 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite. However, '345 teaches (par. 0016) electrodes enlarged by deposition of additional metal … such as gold, and (par. 0052) (s)uitable metals

include aluminum, gold, silver, tin, copper, palladium, platinum, carbon and various metal combinations (reads on noble metal alloy), and '054 teaches (col. 3 lines 17 – 18) electrodes can be made from different conducting materials (e.g. platinum, gold, carbon etc.). Any of the listed metals would be considered to read on the instant claim.

Response to Arguments

8. Applicant's arguments filed 9 September 2011 have been fully considered but they are not persuasive. Applicant's arguments are summarized and Examiner's response follows;

Regarding the rejection of claims 1, 12, 17, and 29 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,635,054 to Girault et al. ("Girault") in view of U.S. Patent Publication 2002/0195345 to Bentsen et al. ("Bentsen");

9. Applicant respectfully argues that Girault fails to disclose or suggest a transducer array containing a flexible metal/isolator composite composed of a metal layer and an isolator layer with a permanent connection between the metal surface and the isolator surface.

However, Girault discloses a flexible metal/isolator composite (col. 1, line 51 and col. 3 lines 17 – 18) *composed of a metal layer* (col. 2 lines 24 – 25, "the conducting material is suitably a thixotropic paste based on carbon *or metallic particles (e.g. platinum or gold)*") and an isolator layer (col. 1 lines 47 – 50) with a permanent connection between a surface of the metal layer and a surface of the isolator layer

("bonded", col. 2 lines 31 – 32, "coated" col. 5 lines 10 – 13 and "2" and "3" of Figs. 1 and 2).

10. Further, argument is made that Girault discloses PVC, and not the "self supporting metal layer" of the instant claims, is that substrate.

The claims are drawn to a biosensor operating on an electrochemical detection principle (a device or product). Examination is therefore based on the final product (the biosensor), not the process by which it was made. Therefore, whether the metal layer was "self supporting" prior to inclusion in the biosensor, or not, it is an integral part of, or structure within, the biosensor of the instant claims.

To the extent that a "self supporting metal layer" can be understood in a structure that comprises metal areas that are electrically isolated from one another, once deposited the metal layer of Girault (col. 2 lines 24 – 25) is capable of being "self supporting".

Finally, the court has held that "if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The biosensor of Girault discloses the structure of the instant application, so Examiner respectfully disagrees with Applicant.

11. Applicant argues that Girault further fails to disclose that metal areas are electrically isolated from one another. Girault discloses (col. 2 lines 23 - 24) "apertures … within an array can be individually addressed to a set electric potential." Individually addressable electrodes are considered to be electrically isolated from one another.

12. Applicant argues that it is unclear how one of skill in the art could modify the device of Girault according to the teachings of Bentsen. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

13. In response to applicant's argument that it is at best unclear how one of skill in the art could modify the device of Girault according to the teachings of Bentsen, and unclear what possible adverse effects the hydrophilic matrix may have on the device of Bentsen, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

14. The Examiner thanks Applicant for the respectful reminder and case law citations and respectfully reminds Applicant that examination proceeds under guidance from the MPEP. See, for example, MPEP 2145 and in particular regard to *In re Hedges* see MPEP 2145 X. D. 3.

Regarding the rejection of claims 1 – 21 and 29 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2002/0195345 to Bentsen et al. ("Bentsen") in view of U.S. Patent 5,635,054 to Girault et al. ("Girault");

15. Applicant argues that Bentsen does not disclose a metal layer being in the form of a self-supporting metal substrate.

The claims are drawn to a biosensor operating on an electrochemical detection principle (a device or product). Examination is therefore based on the final product (the biosensor), not the process by which it was made. Therefore, whether the metal layer was "self supporting" prior to inclusion in the biosensor, or not, it is now an integral part of, or structure within, the biosensor of the instant claims.

To the extent that a "self supporting metal layer" can be understood, in a structure that comprises metal areas that are electrically isolated from one another, the conducting metallic layer *secured* to the polymer layer (par. 0014 of Bentsen, as opposed to the "deposited" metal layer of par.0015) is considered to be capable of being self supporting. Additionally, while the text of Bentsen describes securing the metal layer to the polymer layer, it may be equally appropriate to describe the action as securing the polymer layer to the metal layer.

Finally, the court has held that "if a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim." See, e.g., In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The biosensor of Bentsen discloses the "self supporting metal layer" structure of the instant

application as recited in the rejection of claim 1 and is capable of performing the intended use as a biosensor as recited in the preamble.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN ROSENWALD whose telephone number is (571)270-1149. The examiner can normally be reached on M-F, 8A to 4:30P.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Barton can be reached on (571)272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. R./
Examiner, Art Unit 1759

/Jeffrey T Barton/
Supervisory Patent Examiner, Art Unit 1759
29 September 2011